UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All Cases	)	

MOTION TO MODIFY / LIFT STAY TO PERMIT DEPOSITION OF THE FDA

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") move this honorable Court to lift or modify the stay precluding a meaningful deposition of the FDA at Dkt. 2123.

Introduction

1. The FDA exercised regulatory authority over NECC for more than a decade before this outbreak. The FDA inspected the NECC facility in 2002, and again in 2004. On each occasion, the FDA threatened action against NECC. The threats were hollow. The FDA received specific complaints about NECC's misconduct in 2006, 2007, 2008, 2009, and 2010. With the exception of a single warning letter, the FDA did not make complaints public or take decisive action. And, despite internal FDA documents that demonstrated a plan to re-inspect NECC and take decisive action against NECC, the FDA did nothing.

2. In May 2011, a month before STOPNC first purchased product from NECC, the FDA received a cease and desist Order against NECC issued by the state of Colorado sanctioning NECC for operating illegally. The FDA did nothing.

3. The FDA has (rightfully) admitted that it failed to do its job in regulating NECC.[1] If the FDA had done its job and shut NECC down or required it to operate lawfully – as the FDA is charged to do – the outbreak would not have occurred. The failure of the FDA proximately caused the injuries to the Plaintiffs making claims against the Tennessee Clinic Defendants.[2]

4. The FDA has indispensable information to rebut the Plaintiffs' (incorrect) claim that, had the Tennessee Clinic Defendants simply queried the FDA prior to buying from NECC, they would not have bought from NECC.

5. In addition, since the FDA investigated NECC and made non-public findings consistently from 2002-11, it has discoverable information about NECC's continued efforts to misrepresent its operations to regulators and customers.

[1] Janet Woodcock, MD, Director, CDER (FDA), testimony before Congress, May 23, 2013 (*e.g.*, "we should have been more aggressive….we did not proactively do everything we could").
[2] *See* Dkt. 1455, Answer to Master Complaint, Affirmative Defenses, ¶36-55.

Procedural history / summary of argument

6. The procedural history relevant to this motion is:

a. The Tennessee Clinic Defendants served the FDA with a subpoena for documents and for 30(b)(6) testimony on March 5, 2015.[3]

b. The FDA responded by filing a motion for protective order, asking the Court to issue an order precluding the deposition.[4] The FDA argued that a deposition of the FDA would impede the criminal prosecution of NECC's insiders and that postponing the deposition until after the criminal trial would be most efficient.[5]

c. The Court granted the FDA's Motion for Protective Order.[6]

d. Recently, however, the Court issued an order that indicates an intent to try the first bellwether case before the criminal trial.[7]

7. Because the Order at Dkt. 2123 precludes the deposition of the FDA until after the criminal trial, it will likely be impossible to take the deposition of the FDA before the first bellwether trial, forcing the Tennessee Clinic Defendants to defend the first civil case without this important deposition. This change in circumstances created by the October 7 Order justifies a modification of the protective order.

8. Denying the Tennessee Clinic Defendants information held by the FDA, and denying the jury access to the same information, unjustly prejudices the Tennessee Clinic Defendants. The Court should modify the protective order at Dkt. 2123 to allow a deposition of the FDA before the first civil trial.

[3] Dkt. 1720.
[4] Dkt. 1838.
[5] Dkt. 1838-1.
[6] Dkt. 2123.
[7] Dkt. 2309.

9. In the alternative, the Tennessee Clinic Defendants request that the Court modify the stay in place at Dkt. 2123 to state that the first civil trial will not occur until at least 30 days after the Tennessee Clinic Defendants are able to take this deposition.

Law and Argument

The Court has the power to modify protective orders.

10. "[A] protective order, like any ongoing injunction, is always subject to the inherent power of the district court to relax or terminate the order[.]" *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 535 (1st Cir. 1993).

The Court should modify the protective order to allow the Tennessee Clinic Defendants to depose the FDA prior to the first bellwether trial.

11. The October 7, 2015, Order at Dkt. 2309 reflects a plan to try the first bellwether case *before* the criminal case concludes. This ruling, coupled with the protective order at Dkt. 2123, precludes a deposition of the FDA prior to the first bellwether trial. The prejudice that this creates justifies a modification of the protective order at Dkt. 2123.

12. The testimony of the FDA is very important to several elements of the Tennessee Clinic Defendants' defense of these cases. This has been set out in several briefs.[8] It is important to once again, albeit briefly, revisit the indispensable character of the FDA's testimony:

a. *Comparative fault*: The Tennessee Clinic Defendants have asserted the fault of the FDA as an affirmative defense to the claims against them based, in part, on the wrongful conduct previewed above.[9] If the jury finds the FDA was at fault and caused or contributed to cause the injuries complained

[8] *See, e.g.*, Dkt. 1881, p. 5-6.
[9] *See* Dkt. 1455, Answer to Master Complaint, Affirmative Defenses, ¶36-55.

of, any award of damages against the Tennessee Clinic Defendants will be accordingly decreased.[10] Affirmatively proving the fault of the FDA *without the testimony of anyone from the FDA* is a nearly impossible task. No one can reasonably argue that presenting documents without explanation to the jury and arguing that cold documents prove the fault of the FDA is a viable substitute for the effective cross-examination of a witness. The testimony of the FDA is the best method to prove its fault.

b. *Information relevant to fact defenses*: The FDA has discoverable testimony that will help the Tennessee Clinic Defendants directly rebut the claims against them. The Plaintiffs claim that "readily available" information from the FDA – had the Tennessee Clinic Defendants obtained it before buying from NECC – would have alerted the Tennessee Clinic Defendants to the danger of NECC.[11] The Tennessee Clinic Defendants counter that the only publicly-available ("readily available") information from the FDA about NECC prior to the outbreak was an outdated warning letter that had nothing to do with sterility of injectable medications. Only the FDA can describe what was "readily available" prior to the outbreak.[12] Without the opportunity to cross-examine the FDA, the Tennessee Clinic Defendants will be denied the evidence to decisively debunk the PSC's claim that "[t]he FDA…made it clear...in publicly available documents

[10] *See Owens v. Truckstops of America*, 915 S.W.2d 420 (Tenn. 1996) (holding that, even in product liability cases, comparative fault principles apply if negligence claims also brought).
[11] Dkt. 1902, p. 3 ("Plaintiffs take issue with a host of problems with this cavalier attitude towards patient safety, only one of which is the fact that the Tennessee Clinic Defendants did not also seek readily available information from the FDA").
[12] The PSC also contends, rather remarkably, that the Tennessee Clinic Defendants should have done a FOIA request to the FDA for information on NECC prior to buying from it. (Dkt. 1902, p. 3, n. 5) Only the FDA can clarify what would have been produced in response to a FOIA request in 2011.

that compounding pharmacies posed unique risks when compared to traditional FDA regulated manufacturers."[13]

c. *Information relevant to others' fault*: The FDA holds discoverable information relevant to the fault of others. For example, the FDA's public position has been that the Massachusetts Board of Pharmacy was principally responsible for the regulation of (or, more aptly, the failure to regulate) NECC. Such testimony is directly relevant to prove the comparative fault of the Massachusetts Board of Pharmacy.

13. The Court's October 7 Order dramatically increased the prejudice created by the previous Order at Dkt. 2123. Taken together, the rulings assure that the very important deposition of the FDA will not happen before the first civil trial. Because of this extreme prejudice, the Court should modify the stay to allow the Tennessee Clinic Defendants to take the deposition prior to the first bellwether trial.[14]

14. The Tennessee Clinic Defendants defer to the Court on any modifications to the protective order the Court wishes to make to alleviate any concern that the Government has about impeding the criminal case.[15] Some suggestions include:

a. Requiring the FDA to designate a witness who will not testify at the criminal trial.

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[13] Dkt. 1902, p. 2.

[14] The description of the prejudice that exists in forcing the Tennessee Clinic Defendants to try the first civil case without the necessary depositions is set out in the affidavit at Dkt. 2274-2. All the reasons that it is prejudicial to not be allowed to depose NECC/MSM prior to the first civil trial hold true for the FDA's deposition, too. It may be even more prejudicial to disallow a deposition of the FDA because the Tennessee Clinic Defendants at least now have the opportunity to depose NECC/MSM former employees, obtain a Fifth Amendment invocation, and then argue for an adverse inference. With the FDA, the jury will hear a comparative fault argument with no testimony to accompany it.

[15] Of note, the Tennessee Clinic Defendants likely will subpoena FDA investigators to trial, which will set off another round of motion practice. The more efficient way to secure the testimony is through a 30(b)(6) deposition well before trial, rather than issuing trial subpoenas for a litany of local FDA employees.

b. Limiting the topics to pre-outbreak issues.

c. Expressly barring the criminal defendants from attending the deposition or obtaining the transcript.

15. In the alternative, given the prejudice to the Tennessee Clinic Defendants if they are required to try the first civil case without the deposition of the FDA, the Tennessee Clinic Defendants request an order that the first civil trial will not occur until 30 days after the deposition of the FDA.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 13th day of November, 2015.

/s/ Chris J. Tardio